FEB 0 6 2002

K013730

510(k) Summary of Safety and Effectiveness
Novasys Medical, Inc.

"Ariel" RF Electrosurgical Control Module and Accessories

Intended Use:

The Novasys "Ariel" RF Electrosurgical Control Module and Accessories are intended for use with Novasys Coagulating Electrodes for the coagulation of soft tissue. The system is intended for use by qualified medical personnel trained in the use of electrosurgical equipment.

Submitted by:

Novasys Medical, Inc.
39684 Eureka Drive
Newark, CA 94560-4805
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Contact Person:

Thomas C. Wehman, Ph. D.
Head Quality and Regulatory Affairs
Telephone: (510)226-4068

Date Summary Prepared:

11-2-01

Name of the Device:

Proprietary Name:	Novasys "Ariel" RF Electrosurgical Control Module and Accessories
Common/Usual Name:	Electrosurgical Generator and Accessories
Classification Name:	Electrosurgical Device (per 21 CFR 878.4400)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 0 6 2002

Thomas C. Wehman, Ph.D.
Head, Quality and Reliability
Novasys Medical, Inc.
39684 Eureka Drive
Newark, California 94560-4805

Re: K013730
Trade Name: Novasys "Ariel" RF Electrosurgical Control Module and Accessories
Regulation Number: 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories;
Regulatory Class: II
Product Code: GEI
Dated: November 7, 2001
Received: November 9, 2001

Dear Dr. Wehman:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): ~~Not Yet Assigned~~ K013730

Device Name: NOVASYS "ARIEL" RF ELECTROSURGICAL CONTROL MODULE AND ACCESSORIES

Indications For Use: The Novasys "Ariel" RF Electrosurgical Control Module and Accessories, in combination with various Novasys electrodes, is indicated for the coagulation of tissue.

This device is intended for use by qualified medical personnel trained in the use of electrosurgery.

Contraindications for Use: The use of the Novasys "Ariel" RF Electrosurgical Control Module and Accessories is contraindicated when, in the judgment of the physician, electrosurgical procedures would be contrary to the best interests of the patient.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ (Per 21 CFR 801.109) OR **Over-The-Counter Use** _____ (Optional Format 1-2-96)

Miriam C. Provost

(Division Sign-Off)
Division of General, Restorative and Neurological Devices

510(k) Number K013730